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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/646,111	11/20/2000	Christopher Marriott	REF/MARIOTT/	3979
7590	08/12/2002			
Bacon & Thomas Fourth Floor 625 Slaters Lane Alexandria, VA 22314-1176			EXAMINER	
			TRAN, SUSAN T	
			ART UNIT	PAPER NUMBER
			1615	
			DATE MAILED: 08/12/2002	//

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/646,111	Applicant(s) Marriott
	Examiner Susan Tran	Art Unit 1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on May 14, 2002.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-5, 7-10, 12, 13, and 18-24 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-5, 7-10, 12, 13, 18, and 19 is/are rejected.

7) Claim(s) 20-24 is/are objected to.

8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892)

4) Interview Summary (PTO-413) Paper No(s). 11

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

5) Notice of Informal Patent Application (PTO-152)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s). 12

6) Other:

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DETAILED ACTION

Receipt is acknowledged of applicant's Declaration filed 20/11/00, Preliminary Amendment A filed 11/20/00, Election of Species filed 12/21/01, Request for Extension of Time filed 05/14/02, and Amendment B filed 05/14/02.

Claim Objections

1. Claim 20 is objected to because of the typographical error:

The term "ration" in line 3 should read "ratio". Appropriate correction is required.

Claim Rejections - 35 U.S.C. § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 contains the trademark/trade name "carbopol 93™". Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or

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trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe carbomer and, accordingly, the identification/description is indefinite.

Claim Rejections - 35 U.S.C. § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 8, and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hirao et al. US 4,725,387.

Hirao teaches a process of shaping crystals of sugar alcohols by obtaining a saccharified starch solution with high maltose content, allowing crystallization, and separation (column 2, lines 38 through column 3, lines 1-11). The viscosity of the solution can be regulated by the addition of water-soluble organic solvent, or elevated temperature (column 4, lines 45-68; and example 1). Hirao does not teach the viscosity of less than 25 Pa.s at a shear rate of 1s^{-1} . However, no criticality is seen in the particular viscosity since the prior art obtains the same result desired by the applicant, e.g., a crystalline composition that is non-hygroscopic, free

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flowing, and can be in any desire size and shape (column 7, lines 33-53). Thus, it would have been *prima facie* obvious for one of ordinary skill in the art to, by routine experimentation determine a suitable viscosity of the solution to obtain the claimed invention.

4. Claims 4, 5, and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hirao et al., and Douglas et al. US 5,635,200.

Hirao is relied upon for the reason stated above. Hirao is silent as to the teaching of carbomer as a starch or binder in an aqueous solution. However, carbomer is a well known starch or thickener, or binder in pharmaceutical art. Douglas teaches an oral administration composition comprising starch or carbopol as an aqueous solution thickener (column 7, lines 22-32). Hence, it would have been obvious for one of ordinary skill in the art to modify Hirao's starch solution using carbopol taught by Douglas. The unexpected result is free flowing crystal having desire size and shape.

5. Claims 7, 12, 13, 18, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hirao et al.

Hirao is relied upon for the reasons stated above. Hirao does not teach the specific sugar alcohol, i.e., lactose monohydrate. However, Hirao does teach other sugar alcohols, e.g., sorbitol, maltitol, or maltose monohydrate (columns 2-4). Therefore, it would have been obvious for one of ordinary skill in this art to, by routine experimentation select lactose monohydrate as

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one of the well known sugar to obtain the claimed invention. The unexpected result is a crystalline composition that is non-hygroscopic, free flowing, and can be in any desire size and shape.

Response to Arguments

6. Applicant's arguments filed 05/14/02 have been fully considered but they are not persuasive.

Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for containing the trademark/trade name "carbopol 93™".

Applicant argues that one of ordinary skill in the art would clearly recognize the content of this trademark based upon information well known to one of ordinary skill in the art to which the invention pertains, and therefore, the claim would not be indefinite. As stated in the MPEP§2173.05(u), it is important to recognize that a trademark or trade name is used to identify a source of goods, and Not the goods themselves. Thus a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. See definitions of trademark and trade name in MPEP§608.01(v). See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. *Thus, the use of a trademark or trade name in a claim to identify or describe a material or product would not only render a claim indefinite, but would also constitute an improper use of the trademark or trade name*. In the

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present case, the trademark/trade name is used to identify/describe carbomer and, accordingly, the identification/description is indefinite.

Claims 1-3, 8, and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hirao et al. US 4,725,387.

Applicant points to the MPEP§2143 wherein, to establish a prima facie case of obviousness, the three basic criteria first must be met. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Hirao was cited as a single reference.

In response to applicant's argument that there must be a reasonable expectation of success. In this case, Hirao does suggest the means for adjusting the viscosity, and recognizes the properties desired by the applicant, e.g., crystalline in any desire size and shape that is non-hygroscopic, and free flowing (column 7, lines 33-53).

Applicant argues that Hirao is directed toward a very specific problem, i.e., a method for producing anhydrous crystals of maltitol. There is nothing in the teaching of this document to suggest to the skilled person that this methodology would have wide applicability as does the

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presently claimed invention. Contrary to the applicant's argument, the generic claim of the present application claimed the method of crystallization. The so call "wide applicability as does the presently claimed invention" is not in the claim. The substance being claimed in the generic claim does not exclude maltitol taught by Hirao. It is noted that the feature upon which applicant relies (i.e., wide applicability) is not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicant argues that the fact that a crystalline composition is obtained does not alter the fact that the obviousness of the claimed subject matter must be considered in light of the claim limitations, which includes the viscosity range as set forth in the claims. There must be motivation in the prior art to make the necessary changes to the process and Applicants' specification may not be used as a teaching reference. Contrary to the applicant's argument, the Office Action dated 01/14/02 interpreted the claim in light of the specification, no limitations from the specification were used as a teaching reference. The properties stated, e.g., crystalline in any desire size and shape that is non-hygroscopic, and free flowing is taught by Hirao at column 7, lines 33-53. Furthermore, Hirao at column 4, lines 45-68, teaches the means for adjusting the viscosity as claimed in claim 2 by the applicant. Thus, in response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only

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knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Claims 4, 5, and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hirao et al., and Douglas et al. US 5,635,200.

Applicant argues that silence in a reference is not a substitute for the necessary teaching to arrive at the claimed invention. Contrary to the applicant's argument, although Hirao is silent as to the teaching of the specific starch, *e.g.*, carbomer, Hirao does teach the use of starch and other thickeners (see examples). Furthermore, generic claim does not recite the use of carbomer. Once again, the examiner wish to point out that the limitations disclosed in the Office Action as the unexpected result is disclosed in Hirao at column 7, lines 32-37. Nothing has been taken from applicant's specification.

Applicant argues that Douglas does not teach the use of an aqueous solution of carbomer as being a medium suitable for use in a crystallization process, and therefore, the combination of references does not render the presently claimed invention obvious. In response to applicant's argument, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art.

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See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). The examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Douglas teaches that carbopol can be used in an aqueous suspensions as aqueous solution thickener (column 7, liens 21-34). Accordingly, Douglas is relied upon solely for the teaching of carbopol as an aqueous solution thickener.

Claims 7, 12, 13, 18, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hirao et al.

Applicant argues that there is absolutely no suggestion which would lead one of ordinary skill in the art to make the selection other than applicant own specification. However, since Hirao teaches the use of sugar alcohols, e.g., sorbitol, maltitol, or maltose monohydrate (columns 2-4) to obtain the same result desired by the applicant, it is the position of the examiner that it would have been obvious for one of ordinary skill in this art to, by routine experimentation select lactose monohydrate, because it is one of the well known sugar alcohols in pharmaceutical art. The unexpected result is a crystalline composition that is non-hygroscopic, free flowing, and can be in any desire size and shape (column 7, lines 32-37).

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Claims Allowable

Claims 20-24 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Tran whose telephone number is (703) 306-5816. The examiner can normally be reached on Monday through Thursday from 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

*THURMAN R. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600*